IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

: Hiroshi SUSAKI et al.

Appl. No.

: 09/807.980

Group Art Unit: 1615

(U.S. National Stage of PCT/P99/06016)

Examiner: Unknown

I.A. Filed

: October 29, 1999

For

: DDS COMPOUNDSAND METHOD FOR MEASUREMENT THEREOF

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97, and 1.98, Applicant hereby brings the following information to the attention of the Examiner in charge of the above-identified application, which included information cited and discussed in the specification, in the International Preliminary Examination Report, Written Opinion and International Search Report issued in connection with counterpart International Application No. PCT/JP99/06016. Copies of the International Preliminary Examination Report (in English), the Written Opinion (in Japanese) and International Search Report (in English and Japanese) were submitted with the application.

EP 0 712 635 A1, accompanied by family member U.S. Patent No. 5.658,592:

JP 5-178986 A, accompanied by an English language abstract;

JP 5-222187 A, accompanied by an English language abstract:

JP 6-87746 A, accompanied by an English language abstract;

JP 7-70311 A, accompanied by an English language abstract;

JP 7-228688 A, accompanied by an English language abstract;

JP 7-84481 B2 accompanied by cover sheet of family member WO 92/14759;

JP 8-85703 A, accompanied by an English language abstract;

JP 9-118699 A, accompanied by an English language abstract;

JP 8-319317 A, accompanied by an English language abstract;

JP 2774417 B2, accompanied by family member of JP 5-202085 A, and an English language abstract of JP 5-202085 A;

JP 2774429 B2, accompanied by an English language abstract;

WO 94/19376:

WO 97/46260;

Abstracts of 10th Meeting of the Japan Society of Drug Delivery System. pp. 279 (1994);

Abstracts of 9th Annual Meeting of Japanese Society for the Study of Xenobiotics,

Metabol. And Dispo. Vol. 9, Supplement, pp. \$27, \$27, \$292 (1994);

Abstracts of 19th Seminar of Trends in Research and Development, pp. D-9 to D12, (1995);

Abstracts of 12th Colloid and Interface Technology Symposium, The Chemical Society of Japan, pp. 51-58 (1995); and

Naokazu MURAHASHI et al., "Hepatic Accumulation of Glutamic Acid Branched Neogalactosyllipid Modified Liposomes", Biol. Pharm. Bull., Vol. 20, No. 3, pp. 259-264 (1997).

Applicants also bring to the attention of the Examiner:

Tamio SUGAWARA et al., "Synthesis of 8-Aminooctyl glycopyranosides and of their Conjugates with Poly(L-Glutamic Acid) having a 2-(4-hydroxyphenyl)ethylamino Group for Radiolabeling", Carbohydrate Research, Vol. 238, pp. 163-184 (1993);

Hideki HIRABAYASHI et al., "Development and Pharmacokinetics of Galactosylated Poly-L-GLutamic Acid as a Biodegradable Carrier for Liver-Specific Drug Delivery", Pharmaceutical Research, Vol. 13, No. 6, pp. 880-884 (1996);

Akinori GONSHO et al., "Tissue-Targeting Ability of Saccharide-Poly(L-Lysine) Conjugates", Biol. Pharm. Bull., Vol. 17, No. 2, pp. 275-282 (1994);

Makiya NISHIKAWA et al., "Synthesis and Pharmacokinetics of a New Liver-Specific Carrier, Glycosylated Corboxymethyl-Dextran, and Its Application to Drug Targeting", Pharmaceutical Research, Vol. 10, No. 9, pp. 1253-1261 (1993);

Ruth DUNCAN et al., "Fate of N-(2-Hydroxyproply)Methacrylamide Copolymers with Pendent Galactosamine Residues After Intravenous Administration to Rats", Biochimica et Biophysica Acta, Vol. 880, pp. 62-71 (1986);

Shuji KOJIMA et al., "Tissue Distribution of Radioiodinated Neoglycoproteins and Mammalian Lectins", Biol. Chem. Hoppe-Seyler, Vol. 371, pp. 331-338 (1990); and

Grietje MOLEMA et al., "Neoglycoproteins as Carriers for Antiviral Drugs: Synthesis and Analysis of Protein-Drug conjugates", J. Med. Chem., Vol. 34, pp. 1137-1141 (1991).

Copies of the above-noted documents are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form-1449.

Applicant respectfully requests that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Applicants note that while this Information Disclosure Statement is being filed more than three months from the filing date. Applicants have not received a first action on the merits from the U.S. Patent and Trademark Office. Accordingly, consideration of the enclosed document is required under 37 C.F.R. 1.97(b)(3).

However, if the first action on the merit has been mailed prior to the filing date of this Information Disclosure Statement, Applicants hereby authorize the Commissioner to charge any fees necessary to ensure consideration of the documents cited herein to Deposit Account No. 19-0089.

Applicants also bring to the Examiner's attention the following commonly assigned U.S. applications:

U.S. Application No. 09/147,342 (a copy of which is enclosed), which is a National Stage of PCT/JP97/01914, filed June 5, 1997, and which published as the above-noted WO 97/46420.

U.S. Application No. 09/674,526 (a copy of which is enclosed), which is a National Stage of PCT/JP99/02681, filed May 21, 1999, which published as WO 99/61061 (copy enclosed).

The U.S. applications are submitted for consideration by the Examiner, but are not listed on the Form PTO-1449 as they are not publications.

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Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully submitted, Hiroshi SUSAKI et al.

Arnold Turk Reg. No. 33,094

October 9, 2001 GREENBLUM & BERNSTEIN, P.L.C. 1941 Roland Clarke Place Reston, VA 20191 (703) 716-1191